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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

in re Applica	ation of:)
	Zatezalo et al.)
) Art Unit: 3737
Serial No.	10/757,348)
	,) . Examiner: Jeoyuh Lin
Filed:	January 14, 2004)
)
For: Pro c	GRAMMABLE INJECTOR CONTROL)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This Supplemental Information Disclosure Statement ("IDS") is being filed to comply with 37 CFR §1.56, §1.97, §1.98 and §1.178, and provide the Patent Office with litigation-related documents and the identification of references cited therein by the parties to the litigation entitled *Tyco Healthcare Group LP*, *Mallinckrodt*, *Inc.*, *Liebel-Flarsheim Co.*, *and Nemoto Kyorindo Co.*, *Ltd. v. Medrad*, *Inc.* This case is pending before the United States District Court for the Southern District of Ohio and bears Case No. 1:04cv773 (hereinafter "Ohio Litigation"). The litigation concerns declaratory judgments for non-infringement, the accused infringement by Tyco Healthcare Group LP, Mallinckrodt, Inc., Liebel-Flarsheim Co., and Nemoto Kyorindo Co., Ltd., and invalidity contentions.

The patents involved in the litigation are: U.S. Patent No. 6,643,537 ("the '537 patent"), United States Patent No. 6,339,718 ("the '718 patent"), United States Patent No. 6,336,913 ("the '913 patent"), United States Patent No. 6,676,634 ("the '634 patent"), United States Patent No. 6,743,205 ("the '205 patent"), and United States Patent No. 6,726,657 ("the '657 patent")

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on September 14, 2006.

William L. Warren - Reg. No. 36,714

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(collectively referred to as "patents-in-suit"). This litigation is relevant to the current application because this application is a reissue application of the '718 patent.

Applicants respectfully submit that the references and any litigation related documents and/or materials are made of record to assist the Examiner in the examination of the above-identified reissue application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teachings and relevance to this application.

I. <u>INTRODUCTION</u>

This lawsuit was initiated on November 15, 2004, when Plaintiffs Tyco Healthcare Group LP, Mallinckrodt Inc. and Liebel-Flarsheim Company ("Tyco") filed a declaratory judgment action against Medrad. In its Complaint, Tyco et al. alleged that the '718 patent is invalid, unenforceable and the claims of the '718 are not infringed. Medrad subsequently answered and counterclaimed, alleging infringement by Tyco of Medrad's '718 and '537 patents, as well as, adding the '205, '913, '634 and '657 patents to the case.

In the Ohio Litigation, the parties have filed numerous documents with the court and served numerous documents on each other to support their positions and to rebut the allegations presented by the opposing party. To comply with 37 CFR §1.56, §1.97, §1.98 and §1.178, citations of the Tyco et al.'s Complaint, as well as other litigation documents exchanges by Tyco et al. and Medrad in the Ohio Litigation before and on May 26, 2005 were included in an IDS filed on September 7, 2005. However, the following litigation documents exchanged by Tyco et al. and Medrad, after May 26, 2005 and since the filing of the September 7, 2005 IDS, are listed on the attached Form PTO-1449, and copies of each document are enclosed herewith.

- 1) Tyco's Preliminary Invalidity Contentions filed June 15, 2005
- 2) Tyco's Response to Medrad, Inc.'s Second Set of Requests for Production of Documents and Things filed July 26, 2005
- Defendant Medrad, Inc.'s Brief in Reply to Plaintiff's Response to Medrad, Inc.'s Motion for Leave to File a Second Amended Answer and Counterclaims, filed July 28, 2005

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- 4) Order Granting Defendant's Motion for Leave to File a Second Amended Answer and Counterclaim; Amending Case Management and Scheduling Order filed December 9, 2005.
- 5) Defendant Medrad, Inc.'s Second Amended Answer and Counterclaims, filed January 5, 2006.
- Plaintiffs Tyco Healthcare Group LP's, Mallinckrodt Inc.'s, and Liebel-Flarsheim Company's Reply to Defendant's Second Amended Counterclaims, filed January 27, 2006.
- 7) Defendant Medrad, Inc.'s Second Disclosure of Preliminary Infringement Contentions filed February 3, 2006.
- 8) Medrad, Inc.'s Reply to Plaintiffs' Counterclaims, filed February 16, 2006.
- 9) Medrad Inc.'s Responses and Objections to Plaintiffs' Second Set of Requests for Production of Documents to Defendant, filed February 21, 2006.
- 10) Medrad, Inc.'s Responses to Plaintiffs' Second Set of Interrogatories Nos. 9-14 to Defendant, filed February 21, 2006.
- Plaintiffs Tyco Healthcare Group LP's, Mallinckrodt Inc.'s, and Liebel-Flarsheim Company's, Response to Medrad, Inc.'s Third Set of Requests for Production of Documents and Things (Nos. 48-62), filed February 27, 2006.
- Plaintiffs Tyco Healthcare Group LP's, Mallinckrodt Inc.'s, and Liebel-Flarsheim Company's Responses to Medrad, Inc.'s Second Set of Interrogatories (Nos. 10-15), filed February 27, 2006.
- Plaintiffs Tyco Healthcare Group LP's, Mallinckrodt Inc.'s, and Liebel-Flarsheim Company's Supplemental Preliminary Invalidity Contentions, filed March 3, 2006
- 14) Defendant Medrad Inc.'s Responses and Objections to Plaintiffs' Third Set of Requests for Production of Documents to Defendant, filed March 20, 2006.
- 15) Medrad Inc.'s Responses and Objections to Plaintiffs' Fourth Set of Requests for Production of Documents to Defendant, filed March 22, 2006.

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- 16) Defendant Medrad Inc.'s Second Supplemental Disclosure of Preliminary Infringement Contentions, filed March 24, 2006.
- Plaintiffs Tyco Healthcare Group LP's, Mallinckrodt Inc.'s, and Liebel-Flarsheim Company's Responses to Medrad Inc.'s Fourth set of Requests for Production of Documents and Things (nos. 63-80), filed March 24, 2006.
- 18) [Plaintiffs] Claim Terms to be Construed, filed April 10, 2006
- 19) Defendant Medrad Inc.'s Proposed List of Claims Terms to be Construed, filed April 10, 2006
- 20) Medrad Inc.'s Responses and Objections to Plaintiffs Fifth Set of Requests for Production of Documents to Defendant, filed April 27, 2006.
- 21) Medrad, Inc.'s Witness List, filed May 31, 2006.
- 22) Medrad, Inc.'s Amended Initial Disclosures, filed May 31, 2006.
- 23) Tyco's Witness List, filed June 1, 2006.
- 24) Joint Claim Construction and Prehearing Statement (including Medrad's Brief on Claim Construction and Tyco's Brief on Claim Construction), filed June 8, 2006.
- Plaintiffs Tyco Healthcare Group LP's, Mallinckrodt Inc.'s, and Liebel-Flarsheim Company's Responses to Medrad Inc.'s Third Set of Interrogatories (Nos. 16-18), filed June 8, 2006.
- Plaintiffs Tyco Healthcare Group LP's, Mallinckrodt Inc.'s, and Liebel-Flarsheim Company's Amended Responses to Medrad, Inc.'s Third Set of Interrogatories (Nos. 16-18), filed June 16, 2006.
- Plaintiffs Tyco Healthcare Group LP's, Mallinckrodt Inc.'s, and Liebel-Flarsheim Company's Supplemental Response to Medrad, Inc.'s Interrogatories (Nos. 5-7), filed August 14, 2006.

A brief description of each document follows:

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On June 15, 2005, Plaintiffs filed their preliminary invalidity contentions, stating that each of the '537, the '718 and the '657 are invalid for a variety of reasons. For example, Plaintiffs argued the '718 and the '537 are invalid in view of the Sonic Shot 50 MR Injector by Nemoto (Japan). Another example is that the Plaintiffs argued the '657 is invalid in view of the Angiomat 6000 sold by Liebel-Flarsheim.

On July 26, 2005 Plaintiffs supplied their Response to Medrad's Second Set of Requests for Production of Documents and Things. These requests generally related to the accused products, the commercial offer for sale or release of the accused product, the placement of the product with third-parties, and the prior art asserted in Plaintiffs' preliminary infringement contentions.

On July 28, 2005 Defendant Medrad submitted a Brief in Reply to Plaintiffs' Response to Medrad's Motion for Leave to File a Second Amended Answer and Counterclaims. On December 9, 2005 the Southern District of Ohio granted Defendant Medrad's Motion for Leave to File a Second Amended Answer and Counterclaim. This Order also included an amended Case Management and Scheduling order. Accordingly, on January 5, 2006, Defendant Medrad filed its Second Amended Answer and Counterclaim, adding infringement counterclaims against U.S. Patent Nos. 6,336,913; 6,676,634; and 6,726,657. Each of these included an allegation of willful infringement.

Plaintiffs then replied to the Second Amended Counterclaims on January 27, 2006. Plaintiffs placed defenses on non-infringement and invalidity. Plaintiffs also counterclaimed for a declaratory judgment of invalidity and non-infringement of U.S. Patent Nos. 6,743,205; 6,336,913; 6,676,634; and 6,726,657.

On February 3, 2006, Defendant Medrad filed its Second Disclosure of Preliminary Infringement Contentions, where Medrad alleged that Tyco's OptiVantage DH Injector System ("OptiVantage") literally infringes claims 1-4, 15, 17, 20-21, 26-29, 31-32, 34-38, and 56-62 of United States Patent No. 6,643,537 ("the '537 patent"), claims 1, 4, 5, 7, 10, 14, and 22 of United States Patent No. 6,743,205 ("the '205 patent"), claims 16-23, 27, 34-35, 37-44, 57-65, 67-68, and 72-78 of United States Patent No. 6,339,718 ("the '718 patent"), claims 1-4 of United States Patent No. 6,336,913 ("the '913 patent"), claims 1-4, 6-9, 14-18, 20-21, and 26 of United States

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Patent No. 6,676,634 ("the '634 patent"), and claims 26-35 of United States Patent No. 6,726,657 ("the '657 patent"), as well as alleging that the OptiVantage infringes the claim(s) under the Doctrine of Equivalents. Medrad also asserted the relevant priority dates for each patent. Finally Medrad asserted that its Stellant CT Injection System practices all of the asserted claims of the '537, '718, '205, '913, '634 and '657 patents and the Spectris Solaris MR Injection System practices all of the asserted claims of the '537, '205, '718, '913, '634 and '657 patents.

On February 16, 2006, Defendant Medrad replied to Plaintiffs' Counterclaims, denying each, and praying for the relief of dismissal of Plaintiffs' Complaint, that the patents be found to be valid and infringed, and that such infringement was willful.

On February 21, 2006, Defendant Medrad provided Responses and Objections to Plaintiffs' Second Set of Requests for Production of Documents to Defendant. These requests related generally to prior art and/or other indications of invalidity, the prosecution histories, the design of the accused products in-suit, infringement charts, infringement contentions, damages with respect to the Medrad's products, market studies, business plans and customers. Also on February 21, 2006, Defendant Medrad responded to Plaintiffs' Second Set of Interrogatories Nos. (9-14) to Defendant. These interrogatories included infringement contentions, the accused products, Medrad's products, potential prior art, contentions of objective indicia of non-obviousness and damages.

On February 27, 2006, Plaintiffs responded to Medrad's Third Set of Requests for Production of Documents and Things (Nos. 48-62). These requests generally involved the validity and scope of the patents-in-suit, alleged prior art, comparison of the patents-in-suit with the accused product, changes to the accused product to avoid infringement, notice of the patents-in-suit, non-infringement contentions, sales and profits with respect to the accused products, comparable licenses or agreements, documents related to the Sonic Shot (a similar product), and purchasing incentive programs.

Also on February 27, 2006, Plaintiffs also responded to Medrad's Second Set of Interrogatories (Nos. 10-15). These interrogatories generally related to damages, notice of the patents, non-infringement contentions, invalidity contentions, alleged prior art and inequitable conduct allegations.

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On March 3, 2006, Plaintiffs provided Supplemental Preliminary Invalidity Contentions. Plaintiffs allege the '718 is invalid, at least, in light of the Sonic Shot and the Injektron, both other injector apparatus sold by third-parties. Plaintiffs allege the '205 is invalid, at least, in light of Reilly, U.S. Patent No. 5,520,653, Yamamoto, U.S. Patent No. 6,312,410 and Japanese Publication No. 9-122234. Plaintiffs allege the '913 is invalid, at least, in light of Yamamoto, U.S. Patent No. 6,312,410, the Angiomat 6000 injector, the CT-9000 injector, U.S. Patent No. 5,662,612 and Kleinman U.S. Patent No. 3,964,139. Plaintiffs allege the '634 is invalid, at least, in light of Yamamoto U.S. Patent No. 6,312, 410, the Angiomat 6000 injector, the CT-9000 injector, U.S. Patent No. 5,662,612 and Kleinman U.S. Patent No. 3,964,139. Finally, Plaintiffs allege the '657 is invalid, at least, in light of Reilly, U.S. Patent No. 5,520,653.

On March 20, 2006, Defendant Medrad provided a Second Supplemental Disclosure of Preliminary Infringement Contentions, adding that Medrad's Vistron CT Injection System practices all of the asserted claims of the '913 and '634. Also on March 20, 2006, Defendant Medrad served its Responses and Objections to Plaintiffs' Fourth Set of Requests for Production of Documents to Defendant. These requests had generally related to Medrad's contrast purchasing program, Medrad's discount, rebate, or otherwise reduced price program and Medrad's understanding of any similar programs on the part of Plaintiffs.

On March 22, 2006, Medrad provided its Responses and Objections to Plaintiffs' Fourth Set of Requests for Production of Documents to Defendant. These requests generally related to U.S. Patent No. 6,312,410, Japanese Patent Application No. 7-282129, Japanese Publication 9-122234, correspondence between Medrad, Yamamoto and/or agents of Sugan Co., Ltd., documents related to Yamamoto and/or agents of Sugan Co., Ltd., and documents relating to the inventorship of the '913 and the '634 patents.

On March 24, 2006, Medrad submitted Second Supplemental Disclosure of Preliminary Infringement Contentions, and Plaintiffs also provided their Response to Medrad's Fourth Set of Requests for Production of Documents and Things (Nos. 63-80). These requests generally related to the development of the accused product and any alternatives, the manufacture and production of the accused products, the structure and function of the accused products, any

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patent applications related to the accused products, any competing products and documents which accompany or describe the accused products.

On April 10, 2006, the parties exchanged the terms they believed needed to be construed. On April 27, 2006, Defendant Medrad provided its Response and Objections to Plaintiffs Fifth Set of Requests for Product of Documents to Defendant. These requests generally related to documents concerning the Sonic Shot injector, the Injektron, the AS200 and AS400 (all other injectors in the same market as the products in-suit).

On May 31, 2006, Defendant Medrad produced its initial version of the Medrad Witness List, which included 36 potential witnesses. On the same day, Medrad produced its Amended Initial Disclosures, adding approximately 25 witnesses. On June 1, 2006, Plaintiffs responded with their own witness list.

On June 8, 2006, the parties filed a Joint Claim Construction and Prehearing Statement, which included as attachments each parties' brief on claim construction. In the briefs the parties addressed common issues associated with claim construction – the means plus function rule, prosecution history disclaimer, the use of extrinsic evidence and the like. Also on June 8, 2006, the Plaintiffs provided their Responses to Medrad's Third Set of Interrogatories (Nos. 16-18). These interrogatories had generally related to the prior art allegations with respect to the Injektron and the Sonic Shot 50, as well as any changes to the accused product from the time of prototype to the present. On June 16, 2006, Plaintiffs amended those responses.

On August 14, 2006, Plaintiffs provided a Supplemental Response to Medrad's Interrogatories Nos. 5-7. In this supplement, Plaintiffs included non-infringement charts for the '718, '537 and '205 patents, invalidity contentions and adding alleged prior art references.

To further comply with 37 CFR §1.56, §1.97 and §1.98, Applicants herewith also disclose the following documents which Plaintiffs have cited in reference to the issue of validity of the patents-in-suit (See Tyco's Preliminary Invalidity Contentions filed June 15, 2005; Supplemental Preliminary Invalidity Contentions, filed March 3, 2006):

1. August 3, 2006 Letter from Robert Chambers to Robert Walters re: §102 prior art and attachments.

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- 2. Injektron 82 MRT User Instructions March 10, 1999
- 3. Technischer Bericht December 8, 1997
- 4 Injektron 82 MRT [User Manual] October 1997
- 5. Spectris MR Injector Operation Manual (Medrad waives the confidentiality for this document)
- 6. Nemoto Sonic Shot 5.0 Operation Manual (not submitted permission from opposing counsel not granted) ¹
- 7. U.S. Patent No. 5,569,181
- 8. U.S. Patent No. 6,368,307
- 9. U.S. Patent No. 5,662,612
- 10. U.S. Patent No. 5,520,653
- 11. U.S. Patent No. 6,312,410
- 12. U.S. Patent No. 3,964,139
- 13. U.S. Patent No. 5,865,805
- 14. U.S. Patent No. 5,913,844
- 15. U.S. Patent No. 5,553,619
- 16. U.S. Patent No. 5,662,612
- 17. Japanese Publication No. 9-122234

Applicants believe that certain of the alleged prior art references are not or may not be prior art to the application, and therefore reserve the right to assert that one or more of the references is not prior art to this application. Moreover, Applicants believe they can successfully

A copy of this document is not included with the attached materials because this document was received from opposing counsel during discovery, and is marked "Confidential - Attorneys Eyes Only." We have asked permission to submit the document to the PTO for the purposes of this IDS. However, opposing counsel has yet to agree to the disclosure. If permission is obtained, a copy of this document will be submitted accordingly.

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swear behind many, if not all, of the Section 102 (a) and (e) references based on prior conception and/or reduction to practice.

Nevertheless, Applicants would like the Examiner to at least initially consider the subject matter disclosed in the relevant references vis-à-vis the pending claims because Applicants believe the claims will define over the references.

This Information Disclosure Statement is being filed before a first Office Action on the merit, and therefore, no fee is required under 37 C.F.R. 1.17 (p) for consideration of this Information Disclosure Statement. The Examiner is respectfully requested to initial copies of the attached Form PTO-1449 to show consideration of the references, and to return the initiated forms to the undersigned counsel.

Respectfully submitted

William L. Warren Reg. No. 36,714

SUTHERLAND ASBILL & BRENNAN LLP 999 Peachtree Street, NE Atlanta, Georgia 30309-3996

Phone: 404.853.8000 Fax: 404.853.8806

Attorney Docket No.: 23578-0006

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**EXAMINER: Initial if references considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Senter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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